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HISTOPATHOLOGICAL COMPARISON OF BIODEGRADABLE POLYMER AND PERMANENT POLYMER BASED SIROLIMUS ELUTING STENTS IN A PORCINE MODEL

i2 Poster Contributions
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Authors: *Tobias Koppa, Eric Wittchow, Gerd Bayer, Kristin Steigerwald, Michael Joner, Deutsches Herzzentrum Muenchen, Munich, Germany*

Background: Biodegradable stent coatings might represent a potential solution to overcome sustained inflammatory response limiting long term efficacy and safety of permanent polymer based drug eluting stents.

Methods: Selected biodegradable and permanent polymer based sirolimus eluting stents (SES) formulations were screened for effectiveness in comparison to bare metal stent (BMS) at 28 days. Subsequently, the most favorable SES formulation was compared to commercially available SES (Cypher™) at 28, 90 and 180 days to investigate the histopathologic response as well as tissue, blood and organ pharmacokinetics.

Results: SES with poly L-lactide polymer (PLLA) showed the most favorable outcome with regards to reductions in neointimal area in comparison to BMS (1.3 ± 0.6 mm² vs. 1.7 ± 1.1 mm², p=ns) at 28 days. The PLLA SES showed a similar reduction in neointimal area compared to Cypher™ at 28 days, with significant greater reductions at 90 and 180 days (1.7 ± 0.7 mm² vs. 3.1 ± 1.5 mm², p=0.03 and 1.8 ± 1.2 mm² vs. 3.0 ± 1.5 mm², p=0.01, respectively).

Conclusions: The use of PLLA as drug-eluting matrix resulted in mild inflammatory responses in the presence of effective sirolimus tissue concentrations. The greater efficacy observed at long term follow-up in PLLA SES compared to Cypher™ may be attributed to polymer biocompatibility.

PEVA/PBMA Sir PUR Sir PLLA Sir PLGA Sir

